

2 the second leaflet each include an inner edge having a first end
3 connected to the first bend and a second end connected to the second
4 bend.

REMARKS

In the Office action of May 5, 2004, Paper No. 40, claims 1,2,4-13,15,16, and 55-65 were pending with claims 3,14, and 17-54 having been withdrawn from consideration. Claim 59 was allowed and all other pending claims stood rejected. Claims 6 and 13 were indicated to be allowable if rewritten in independent form. In particular, claims 8,64, and 65 were rejected under 35 U.S.C. 112, second paragraph as being indefinite. Claims 1,2, 7-9,12,60,61 and 63-65 are rejected under U.S.C. 102(e) as being anticipated by Andersen et. al. Claims 1,2,4,5,7-9,12,58,60, and 63-65 are rejected under U.S.C. 102(e) as being anticipated by Moll et. al. Claims 10,11,55-57, and 62 are rejected under U.S.C. 103(a) as being unpatentable over Andersen et al. in view of Cox. Claims 15 and 16 are rejected under U.S.C. 103(a) as being unpatentable over Andersen et al. in view of Bessler et al. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moll et al. in view of Bessler et al.

Claim Objections

The informalities of Claims 7,60, and 61 are being corrected as requested by the Examiner.

Claim Rejections 35 USC § 112

Claim 8 is being amended to depend from Claim 7, thereby fixing the antecedent problem of 'integral, one-piece member'. In Claim 64, the 'side' is changed to 'interconnected sides', thereby addressing that antecedent problem.

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Claim Rejections 35 USC § 102

Examiners' Point 7 (Andersen et al.):

Claim 1 is being amended to more explicitly call out the relationship of the outer edge of the leaflet to the side elements of the support structure and how outer edge engages the wall of the bodily wall. The claim now reads: 'the outer edge of each one of the plurality of leaflets includes an attachment extending along at least selected ones of the side elements such that the outer edge is adapted to resiliently and sealingly engage the wall of the bodily passage along said path. . .'. The language 'extending along' was suggested by Examiner Willse during the personal interview conducted at the USPTO on April 15, 2004. Clearly, the valve of Andersen is mounted inside the support structure. To mount the valve, Andersen discloses only that 'the valve 6 is mounted in the stent by means of a suitable number of sutures to form the cardiac valve prosthesis'. By definition, having the attachment extending along a side element requires that the outer edge and side element co-extend for some distance, which makes the outer edge 'adapted to resiliently and sealingly engage the wall of the bodily passage' along the prescribed path. Andersen's leaflet outer edge does not co-extend with or get carried by a side element of the stent and, thus could not have an attachment extending along a side element as required by the claim.

It also should be noted that in Claim 1, some redundant language concerning the configuration of the path formed by the side elements was deleted from the claim in addition to the other amendments described for Claim 1.

With respect to claim 7 and dependent claims 8 and 9, Andersen does not disclose that the leaflet body and frame could comprise an single, integral member. Rather, all embodiments disclose a support structure with a valve mounted in it. Furthermore, Andersen does not teach a generally flat shape in any disclosed valve configuration.

With respect to claims 12 and 60, each is being amended to call for a bi-leaflet valve. Claim 12 is dependent upon Claim 1, which is being amended to further distinguish over Andersen. As for Claim 60, the plurality of outer edges

engage the wall of the bodily passage and are distinguished from Andersen in that they 'form a seal . . . along a pathway defined by the plurality of interconnected side elements'. Andersen clearly does not disclose the side elements forming a pathway along the wall of the passage that comprises any sort of seal.

Claims 61 and 63-65 are dependent

Examiner's Point 8 (Moll et al.)

As suggested by Examiners Willse and Blanco during the personal interview of April 15, 2004, Claim 1 is being amended to more explicitly describe the relationship between the passage wall, the leaflet, and the fluid trapped therebetween. Instead of merely calling for the fluid to be trapped between the leaflet and wall, the claim now requires that the fluid be trapped against the wall. Clearly, the Moll valve traps fluid within cones which abut the vessel wall and thus, the vessel wall is not open and available for the inner portion of the cone to trap fluid against it.

With respect to Claim 4, Moll does not teach an overhang of material extending along the outer edges of the leaflets as they extend along and are attached to the side elements of the frame. In fact, Moll does not teach that the leaflets, which actually comprise pockets, are attached to the frame at all. It appears from the drawings that they are merely slipped over the frame and held in secured in that manner, rather than the frame being attached along the outer edges of the pockets (however the 'outer edges' might be defined).

With respect to claim 5, the outer edges of the pockets, whatever they might be, are clearly not attached to the wire frame as required by the claim. It is the configuration of the pocket, which surrounds the frame, that causes the engagement thereto.

Like Andersen, Moll does not disclose an integral, one-piece member which includes both the frame and leaflet body as one piece. Therefore, Claims 7-9 are not anticipated.

With respect to Claim 12 and 60, the claims have been amended to

require 'a pair of opposing leaflets' as discussed under the response to Examiner's Point 7. Moll only teaches a valve that includes three pockets and thus, cannot anticipate either claim 12 or 60.

With respect to Claim 58, Moll does not teach an embodiment in which the valve can assume a flat configuration as the Examiner claimed in rejecting Claim 58. Figure 2 of Moll depicts an unassembled frame before it is formed into a valve and thus, does not apply. Applicants teach a flat configuration embodiment that can be folded along two axes to form a functioning valve. Furthermore, Moll does not teach that the leaflet includes a wall-engaging outer edge that is reinforced by one of the plurality of legs. Any outer edge, however it is defined, of the Moll 'pocket' does not co-extend with a leg or portion of the frame. The portion contacting the leg frame is neither an edge, nor is attached in a manner than could describe it as being 'reinforced'.

With respect to the amendments and arguments presented above, it is felt that the current claims are clearly not anticipated by either Andersen et al. or Moll et al. Therefore, favorable consideration of these claims is requested.

Claim Rejections 35 USC § 103

Examiner's Points 10 and 11:

The Examiner maintains that it would be obvious for a skilled person to take the small intestinal submucosa material (SIS) taught by Cox, preferably resected or harvested from the patient during the same operation to replace the valve (Col. 20, lines 43-48), forming it into leaflets, and attaching it to a valve prosthesis for implantation into a bodily passage. The preferred technique taught in the Cox patent is for the surgeon to harvest the SIS material and then form it into an artificial mitral or tricuspid valve having a tubular shape during the operation by how it is sutured in place. Although packaged, sterilized SIS attached to an simple annuloplasty ring is mentioned as an alternative, Cox clearly states in Col 19, lines 4-8 that previous artificial (xenographic) tissue valves that include a stent and which mimic native valves (i.e., they comprise leaflets

rather than Cox's tubular design) cause blood flow turbulence leading to calcification. Thus, Cox clearly teaches away from the concept of using a valve having SIS attached to an implantable expandable frame to form leaflets. In Cox's view, it is the surgically created tubular valve that overcomes the blood turbulence problem and thus, the Moll and Andersen support structures would not be deemed suitable alternatives. Moll suggests that PTFE is the preferred material to form the cone-shaped 'blood stoppage elements' (Col.3, lines 41-44) and does not mention the possibility of using a biologic material, let alone a material having a specialized function such as a remodelable material, such as a remodelable ECM. Andersen discloses a 'tissue valve' such as a 'cleaned' porcine valve harvested from a slaughtered pig (Col. 5, lines 29-39). Being a natural valve, it is anatomically suitable to replace a human valve. Nowhere does Andersen suggest forming a valve from a tubular structure in the fashion of Cox, nor from any biological material that doesn't already comprise a natural valve. Since neither reference provides any suggestion or motivation to combine the separate teachings that would result in Applicants' invention, and because the Cox reference actually teaches away from the combination, it should be clear that the present claimed invention is not obvious over Moll or Andersen in view of Cox. Favorable consideration is thus requested.

Examiner's Points 12 and 13:

For the reasons stated above in the response to Examiner's Points 7 and 8, the Andersen and Moll references do not anticipate Claim 1, from which Claims 15 and 16 depend, Therefore, neither Andersen nor Moll includes teachings that can be combined with that of Bessler to render either of these claims obvious.

Allowable Subject Matter

The Examiner has indicated that Claim 59 is allowed and that Claims 6 and 13 would be allowable if rewritten in independent form. Applicants appreciate the favorable determination of allowability, but have elected to amend

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Claim 1 instead and keep claims 6 and 13 as depending claims.

New Claims

New claims 66 and 67 are being presented for the first time. Claim 66-67 are directed to a bi-leaflet valve having other features concerning the attachment and configuration of the bends, leaflets, and side elements. These claims are also patentably distinct from the cited references. Therefore, favorable consideration of these claims is requested.

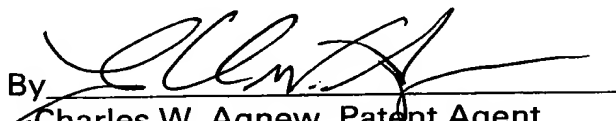
*Confirmation Copy*Summary

By this action, claim 1-2, 4-6, 10-13, 15-16, and 55-67 are now pending in the application, claims 66-67 having been added as new. Claims 1,7-8,12,60,61, and 64 are being amended. The reexamination and reconsideration of the claims of this application is respectfully requested, and it is further requested that the application be passed to issue. If any issues remain after the Examiner has considered this amendment, it is being requested that the Examiner please telephone Applicants' representative, Mr. Agnew, to discuss setting up a personal interview.

Respectfully submitted,

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